SEP - 6 2000 K002001

1 Summary of Safety and Effectiveness

A summary of the safety and effectiveness has been prepared for the Breeze SleepGear with DreamSeal (DreamSeal) in accordance with the Safe Medical Device Act of 1990. This summary is stated below.

1.1 Manufacturer Name, Address, and Registration Number

Puritan-Bennett
2800 Northwest Blvd.
Minneapolis, MN 55441 USA
763-694-3500

Registration number: 1933149

1.2 Proprietary Name of Device

Breeze SleepGear with DreamSeal

1.3 Common Name of Device

Accessory, non-continuous ventilator

1.4 Device Classification

21 CFR 868.5905
Product code: 73 BZD
Class II

1.5 Intended Use

The DreamSeal is a patient interface accessory intended for use with devices that administer CPAP (continuous positive airway pressure) and bi-level positive airway pressure in treating adult patients.

1.6 Device Description

The DreamSeal is a nasal CPAP mask intended for the delivery of CPAP or bi-level positive airway. The mask and tubing are connected to the CPAP or bi-level and the patient. The positive pressure forces the patient-exhaled gasses through a hole on the mask as new air is brought into the breathing circuit from the CPAP or bi-level machine.

The DreamSeal forms a seal around the patient's nose using soft, molded silicone. This silicone seal is removable and can be replaced as the softness, comfort, and fit wears out. The seal snaps into a rigid shell, which then completes the mask assembly. The mask assembly is connected to the tubing, which is connected to the CPAP machine.

1.7 Predicate Device and Performance Testing

The predicate device is the Nasal CPAP Mask (renamed SoftFit Ultra), 510(k) number K942246. Performance testing against the SoftFit Ultra shows comparable performance for vent flow, static and dynamic regulation, work of breathing, and dead space calculations. There are no FDA mandated performance standards.

1.8 Conclusion

Puritan-Bennett concludes that the DreamSeal meets its stated specifications, will operate safely in its intended environment, and will be effective in fulfilling its intended use. The results of performance testing shows this device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2000

Mr. Darin L. Busch
Puritan-Bennett Corp.
2800 Northwest Boulevard
Minneapolis, MN 55441

Re: K002001
Breeze SleepGear with DreamSeal
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: August 4, 2000
Received: August 7, 2000

Dear Mr. Busch:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Intended Use

Device Name:

Breeze SleepGear with DreamSeal

Intended Use:

The Puritan-Bennett DreamSeal is intended for use with devices that deliver Continuous Positive Airway Pressure (CPAP) and bi-level positive airway pressure in treating adult patients.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____

510(k) number: K002001

(Revised 8-4-00)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002001